REMARKS

The Office Action

Applicants acknowledge the Examiner's withdrawal of the 35 U.S.C. §101 double patenting rejection of claim 19 as well as the withdrawal of the 35 U.S.C. §102(b) rejection of claims 19-20 and 36.

New Rejections

35. U.S.C. §102(b) – U.S. Patent 2,965,575

The Examiner has rejected claims 19-20 and 36 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent 2,965,575 ("the '575 patent"). Specifically, the Examiner states that the compositions of various examples in the '575 patent anticipate the claimed compositions and that use of two or more compositions is allegedly well known in the pharmaceutical art. Applicants traverse.

The pending claims recite a pharmaceutical composition that requires a compound and a pharmaceutically acceptable carrier, adjuvant, or vehicle. See, e.g., claim 19. The application defines a "pharmaceutically acceptable carrier or adjuvant [as] a carrier or adjuvant that may be administered to a patient, together with a compound of this invention, and which does not destroy the pharmacological activity thereof and is nontoxic when administered in doses sufficient to deliver a therapeutic amount of the compound" (page 45, lines 24-34). The Technical Field of the Invention teaches that the claimed pharmaceutical compositions may be advantageously used as therapeutic agents for inosine-5'-monophosphate dehydrogenase (IMPDH) mediated processes (page 1, lines 9-12). More

specifically, the application discloses that the claimed pharmaceutically acceptable compositions are useful as IMPDH inhibitors and can be used for the treatment or prophylaxis of transplant rejection and autoimmune disease (page 6, lines 5-11). Finally, the application teaches that the claimed pharmaceutical compositions are useful as multi-component compositions with other therapeutic and prophylactic agents for antiviral, anti-tumor, anti-cancer, anti-inflammatory, antifungal, antipsoriatic immunosuppressive chemotherapy and restenosis therapy regiments (page 6, lines 12-17).

The '575 patent teaches none of those things. It provides absolutely no disclosure that its compounds, e.g., the compound of Example 1, are useful as a part of a pharmaceutical composition. Nor does the '575 patent teach using any compounds with a pharmaceutically acceptable carrier. Rather, the '575 patent discloses compounds that are employed in detergent compositions or detergent base cosmetic compositions ordinarily used to beautify, cleanse or protect the skin. See, e.g., column 4, lines 59-63. In that use, the compounds of the '575 patent have antiseptic properties. See, column 4, line 69-70; claims 1 and 2. And, in those uses, no pharmaceutically acceptable carrier, adjuvant or vehicle is used or suggested. Rather, the compounds of the '575 patent are preferably admixed with a detergent base. Indeed, the preferred embodiment of the '575 patent incorporates its halogen substituted benzanilides in an alkali metal fatty acid soap, specifically an "Ivory" brand neutral high grade white toilet soap. See, column 3, lines 6-12.

Thus, nothing within the four corners of the '575 patent discloses using its compositions in therapy or as part of a pharmaceutical composition. For anticipation, a

patent must disclose "each and every element of the claim". The '575 patent does not. Accordingly, the '575 patent cannot and does not anticipate the pending claims. Applicants request that the Examiner reconsider and withdraw this rejection and allow claims 19-20 and 36.

35 U.S.C. §103(a) - Obviousness

Claims 19-20 and 36 stand rejected under 35 U.S.C. §103(a) as being allegedly obvious over the '575 patent. According to the Examiner, the '575 patent refers to structurally similar compounds for use in pharmaceutical compositions. See, e.g., Examples 1 and 2. The Examiner acknowledges that the '575 patent "has not made exact compositions as claimed [in the present invention]". The Examiner asserts, however, that it would have been obvious to obtain the compositions of the present invention with the generic disclosure in the '575 patent because the '575 patent "is teaching similar compositions" to those claimed in the present invention, and the use of the two or more combination of compositions is referred to in the '575 patent in column 1-2, lines 42-50. Applicants traverse.

The '575 patent does not refer to pharmaceutical compositions. It refers to detergent compositions. Indeed, the specific compounds of Examples 1 and 2, to which the Examiner has pointed, are combined with detergent bases, not pharmaceutically acceptable carriers, as required by the pending claims. There is absolutely no suggestion in the '575 patent that the specific compounds of Examples 1 and 2 are useful as drugs or should be combined with pharmaceutically acceptable carriers. Furthermore, because there is no

teaching that the compounds of the '575 patent have pharmaceutical activity, the '575 patent cannot be combined with any other document describing a pharmaceutically acceptable carrier. The skilled worker would have no motivation to make such combination nor would the documents themselves suggest such a combination.

Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Obviousness-Type Double Patenting – U.S. Patent 6,653,309

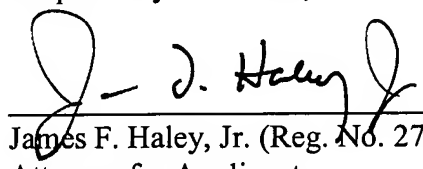
The Examiner has rejected claims 19, 20 and 36 for obviousness-type double patenting over claim 19 of U.S. Patent 6,653,309 ("the '309 patent"). The Examiner acknowledges that the conflicting claims of the instant application are not identical to claim 19 of the '309 patent. However, the Examiner alleges that claims 19, 20 and 36 are not patentably distinct from claim 19 of the '309 patent because the definition of X in the instant claims overlaps with the corresponding definition in the '309 patent and "it is well known to add additional ingredient to any composition to treat a disease".

Applicants stand ready to file one or more terminal disclaimers, in compliance with 37 C.F.R. §1.321(c), to obviate the obviousness-type double patenting rejection upon allowance of any of the conflicting claims in this application.

CONCLUSION

Applicants request that the Examiner consider the above remarks, withdraw all the outstanding rejections, and allow the pending claims 19-20 and 36 to pass to issue.

Respectfully submitted,



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